

**Testimony of  
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**Testimony Before the  
Committee on Health, Education, Labor, and Pensions  
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Good morning. I am Marjorie Speers, Executive Director of the Association for the Accreditation of Human Research Protection Programs, known by its acronym, AAHRPP. I am the former Acting Executive Director of the National Bioethics Advisory Commission (NBAC). While at NBAC—which had a charter that expired on October 3, 2001—I was the Project Director for a comprehensive report on human research oversight entitled “Ethical and Policy Issues in Research Involving Human Participants.” That report was presented to the President on August 20 of last year. In my NBAC capacity, I would like to share several of the major recommendations from that report with you today.

Clearly, scientific investigation has extended and enhanced quality of life, and is one of the foundations of our society’s economic, intellectual, educational, and social progress. In particular, great strides have been made in human research, including the social sciences, the humanities, and the biomedical sciences. The American research enterprise is the leader—not to mention the envy—of the international scientific community.

As these capabilities and knowledge areas have developed so rapidly, the research community has been challenged to keep pace with the ethical and moral implications and operations of its work. NBAC was not alone in its deliberations on this matter; numerous studies addressing participant protection have been conducted by both governmental and private organizations, including the Institute of Medicine, the General Accounting Office, the Office of the Inspector General in the Department of Health and Human Services, the Association of American Medical Colleges, and the Association of American Universities. All of these studies have underscored the need for more careful, thoughtful, systematic human research participant protections.

In preparing its report, NBAC scrutinized the adequacy of the entire system for protecting human research participants, focusing on the current patchwork of regulations described as the “Common Rule” and examining the full range of research with human beings sponsored by both the federal government and the private sector. The final report proposed 30 recommendations for changing the oversight system at the national and local levels that would ensure all research participants receive appropriate protections and remove unnecessary burdens; today, I will focus on three recommendations that are essential to improving protection.

Recommendations 2.1, 2.2, and 2.3 are the crux of NBAC’s findings. “Recommendation 2.1: The federal oversight system should protect the rights and welfare of human research participants by 1) independent review of risks and potential benefits and 2) voluntary informed consent. Protection should be available to participants in both publicly and privately sponsored research. Federal legislation should be enacted to provide such protection.”

This recommendation is vitally important because it responds to concerns about research conducted by federal agencies that do not follow the Common Rule or privately funded research that is not regulated by the Food and Drug Administration (FDA). In both scenarios, research participants are simply not protected by the current oversight system. It is ethically indefensible to not protect each and every participant in research.

Implementing such a recommendation, however, is quite difficult given the current organization of our oversight system, which leads to Recommendations 2.2 and 2.3.

“Recommendation 2.2: To ensure the protection of the rights and welfare of *all* research participants, federal legislation should be enacted to create a single, independent federal office, the National Office for Human Research Oversight (NOHRO), to lead and coordinate the oversight system. This office should be responsible for policy development, regulatory reform (see Recommendation 2.3), research review and monitoring, research ethics education, and enforcement.”

“Recommendation 2.3: A unified, comprehensive federal policy embodied in a single set of regulations and guidance should be created that would apply to all types of research involving human participants (see Recommendation 2.2).”

These two recommendations are key pieces to building a comprehensive research oversight system with policies that can be consistently and uniformly applied. The Common Rule is separately codified in regulation by 15 federal agencies and followed by two other federal agencies under an executive order and public law, but a number of other federal agencies that conduct research do not comply with the Common Rule. Even within the 17 agencies that follow the Common Rule, differences exist among the agencies in how they apply the Common Rule. NBAC discovered, for example, that regulatory coverage for vulnerable populations in research, such as children, is inconsistent across the federal government, which is particularly worrisome given that most federal departments conduct research involving individuals who are in some way vulnerable.

NBAC stood strongly behind the need to establish a single, independent federal office with the authority to issue a single set of regulations and guidance. This recommendation is not meant as a criticism of the Office of Human Research Protection within the Department of Health and Human Services; rather, NBAC recognizes the need for a federal office to exist independently *and* outside of a federal department or agency that sponsors research and be responsive to the ethical issues of all fields of research, not just those of primary concern to the Department of Health and Human Services. Such an office can be responsive to the changing needs of the research system, revising policy as necessary, and serving as a centralized enforcement authority. Currently there is no effective means to do so; the agencies who are signatories to the Common Rule have not been able to make changes to it in the last 11 years even though the need for changes has existed.

Regulations should address basic ethical standards that are common across all research types, such as informed consent, vulnerability, and privacy and confidentiality. In addition, guidance should be offered that assists in interpreting basic regulations in different areas of research. A wide variety of research, from clinical trials to social science methods, is currently regulated under the same set of federal rules. However, these rules were originally written at the National Institutes of Health and do not always appropriately address the ethical issues in research outside of the biomedical context. With fewer and flexible regulations and more appropriate guidance on how to apply the regulations to different types of research, the oversight system recommended by NBAC would be more responsive to investigators' and participants' concerns.

While NBAC's primary goal was to make recommendations that would improve protections for research participants, it was also interested in identifying ways to reduce the unnecessary burdens within the current oversight system. Federal regulation and guidance should require ethics review and oversight that is commensurate with the nature and level of risk in the research. For example, NBAC recommended that the regulations should permit institutions to use approval procedures other than full IRB review when research involves no greater than minimal risk.

Adopting NBAC recommendations would go far in ensuring the protection of research participants in a manner that encourages and facilitates research that is consistent with accepted ethical principles.

Finally, the NBAC report strongly reinforces the need for a culture of concern and respect in the entire research community. An oversight system will succeed to the extent that those involved in human research recognize their ethical obligations to protect participants. The NBAC report recommends that the federal government and professional organizations promote educational training in human research protection, certification for individuals, and accreditation for institutions. If this cultural shift can occur, we will arrive at a comprehensive, flexible system based on ethical principles and focused on ethically substantive requirements that should maximize protections for research participants.

The responsibility for protecting research participants is a shared one. The government and the private sector, universities in particular, have important roles to play. I'm here today to also testify on behalf of a new, private sector organization, AAHRPP.

From my years of overseeing research, to my role at NBAC, to my current position at AAHRPP, it has become clear to me that there is no single problem with the current oversight system for protecting research participants crying out for urgent repair, but there are several problems that need to be corrected in a comprehensive manner. This is a time for a fresh start, and for us to examine all aspects of the oversight system.

In addition to the three major recommendations that I outlined from the NBAC report, the Commission took a stand in favor of accreditation: "Recommendation 3.4: Sponsors, institutions, and independent Institutional Review Boards should be accredited in order to conduct or review research involving human participants. Accreditation should be premised upon demonstrated competency in core areas through accreditation programs that are approved by the federal government."

AAHRPP uses a voluntary, peer-driven, educational model of accreditation. By requiring institutions to meet an explicit set of standards for protection, AAHRPP's goals are to recognize institutions that meet these high standards and assist the research community in continuously improving its efforts to protect the rights and welfare of research participants. We believe that voluntary self-regulation by the research community, along with oversight by an independent accrediting body, is the best strategy for making research as safe as it possibly can be.

The history of accreditation shows that it is successful when it arises from the concerns of professionals engaged in the field, such as in higher education. AAHRPP was founded by seven organizations that bring diverse perspectives to this new enterprise: the Association of American Medical Colleges, representing medical schools, teaching hospitals, and academic societies; Association of American Universities, representing major research-intensive universities; Consortium of Social Science Associations, advocating on behalf of social and behavioral science organizations; Federation of American Societies of Experimental Biology, the Nation's largest coalition of biomedical research organizations; National Association of State Universities and Land Grant Colleges, representing public universities and land-grant institutions; National Health Council, representing patient and health-related groups; and Public Responsibility in Medicine and Research, respected for its more than 3 decades of improving ethics in both medicine and research through education. The views of research participants, the public, investigators, and sponsors of research have been represented since AAHRPP's inception, and that diverse representation continues on our 21-person Board of Directors, our Council on Accreditation, and among our site visitors.

Now is the time for accreditation to take hold. The time is right for several reasons: first, the government has provided leadership and clear guidance that accreditation has real potential for improving performance and quality, and that it should be undertaken. Second, the government has exercised its enforcement options. Highly publicized shutdowns of large research programs at academic institutions in the past several years captured the attention of the research community – and the Nation, and made it clear that federal regulations for protecting research participants were to be taken seriously.

Over the last year, with recognition by the research community of the need to improve human research protections and the desire to move deliberately and swiftly, AAHRPP has taken governmental policy and developed it, with the input from a diverse range of professionals and the public, into a clear set of accreditation standards. As the NBAC report states, "The choice of standards for these [accreditation and certification] programs and the criteria for evaluating whether an institution has met them are critically important."

AAHRPP's standards meet all regulatory requirements and, in some cases, exceed them. With these comprehensive standards, we can raise the level of protection beyond the minimal level set by the government. AAHRPP's standards are significant in several other respects: they are broad and flexible so that they will be meaningful to a full range of research types; certainly in clinical research, but also in social science, historical, and business research. The standards can be applied in a variety of research settings, including universities, hospitals, government agencies, and independent institutional review boards. Finally, the standards make clear that protecting research participants is not the sole responsibility of the IRB, but a duty shared by everyone who conducts research. Entities seeking accreditation must meet standards that address the obligations relating to the organization, IRB, investigator, sponsor, and participant. This is an important point, as much of the dialogue and debate on human research protections has focused on the role and function of the IRB. While there is no doubt of the key role played by IRBs, AAHRPP believes strongly that the protection of human research participants is a collective responsibility of the entire research community, beginning with institutional leadership and extending to the most junior staff.

With the introduction of these standards, institutions now have a clear idea of the high expectations they must meet. And because they know the government recognizes accreditation as a valuable means for enhancing human research protections, accreditation will be eagerly embraced.

In closing, I'd like to say that the accreditation of human research protection programs is not a panacea. But in conjunction with other efforts underway and other recommendations yet to be implemented, accreditation has an important place in the overall scheme. The benefits of accreditation seem clear: improving protection programs across the entire research community, making research safer and reducing unnecessary harm, and ultimately, preserving and justifying public confidence in research. Thank you for the opportunity to address the committee.

## REFERENCES

"Ethical and Policy Issues in Research Involving Human Participants," Vol. I, Report and Recommendations of the National Bioethics Advisory Commission, Bethesda, Maryland, August 2001.